

Univers

CA Humeral Heads



SURGICAL TECHNIQUE

Arthrex® 

UNIVERS™ CUFF ARTHROPATHY HUMERAL HEADS

DESIGN RATIONALE

The Univers Cuff Arthropathy Humeral Head System is intended for hemiarthroplasty applications when treating end-stage rotator cuff arthropathy, for which reverse shoulder arthroplasty is not indicated. The implants are designed to articulate with the native glenoid and acromion, allowing for smooth range of motion.



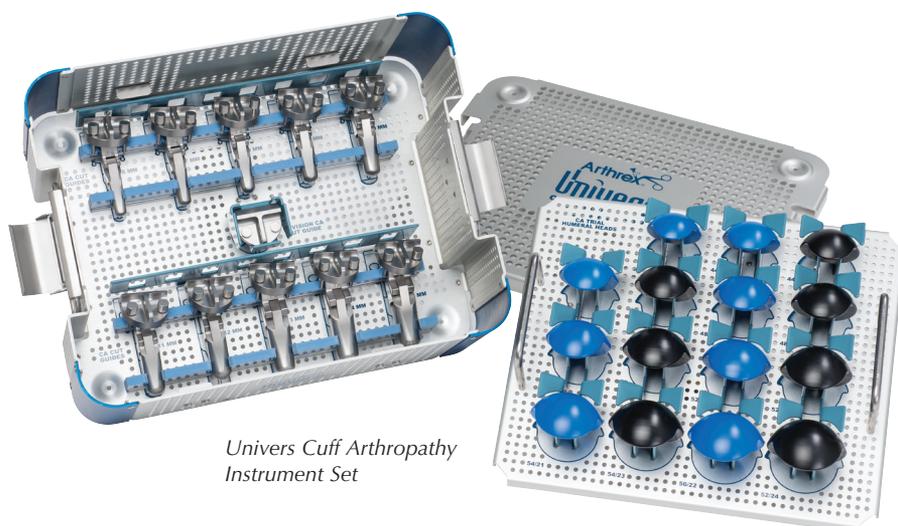
IMPLANT FEATURES

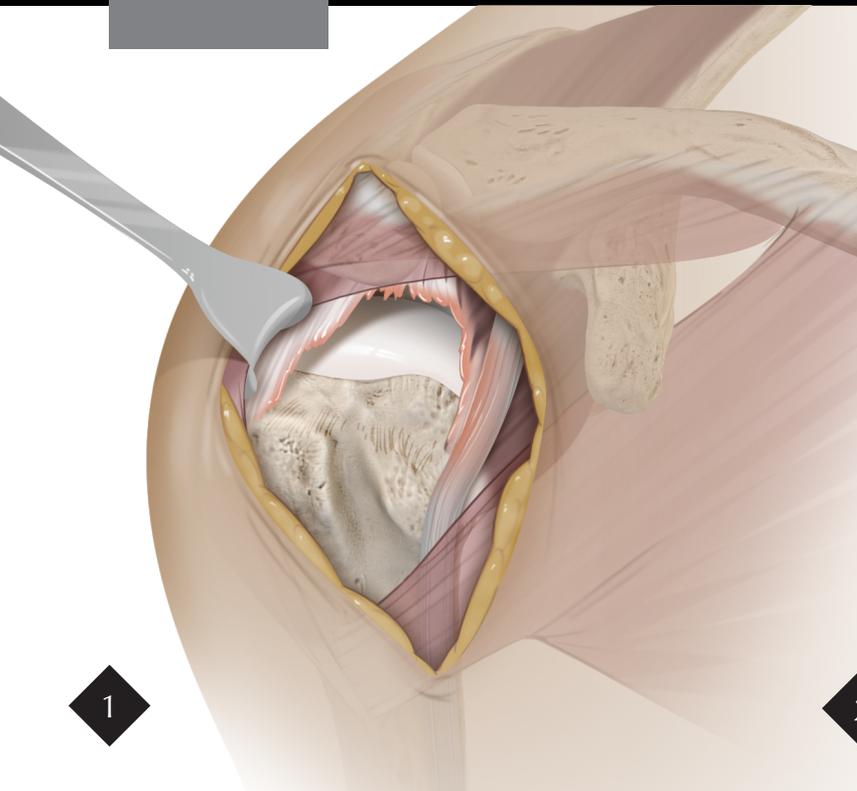
- Compatible with the Univers™ II, Univers Apex, and Univers Fracture total shoulder systems
- Head sizes from 42 mm to 56 mm
- Standard and +2 mm head heights



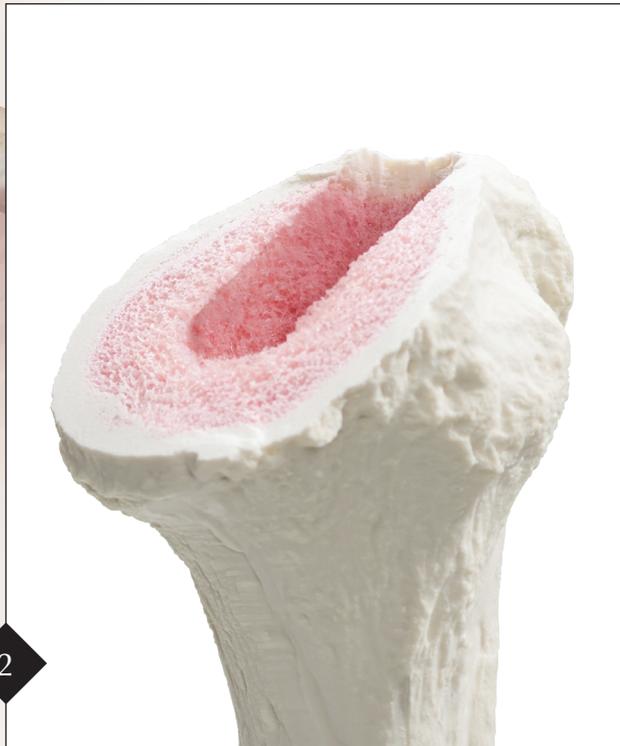
INSTRUMENT SET FEATURES

- Single, simplified instrument case
- CA Cut Guides for both primary and revision scenarios
- Complete suite of trial heads matching all head implant offerings

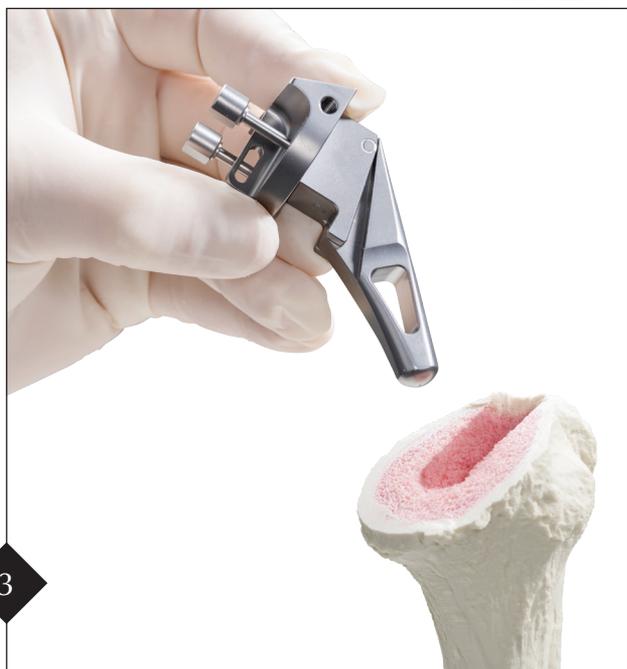




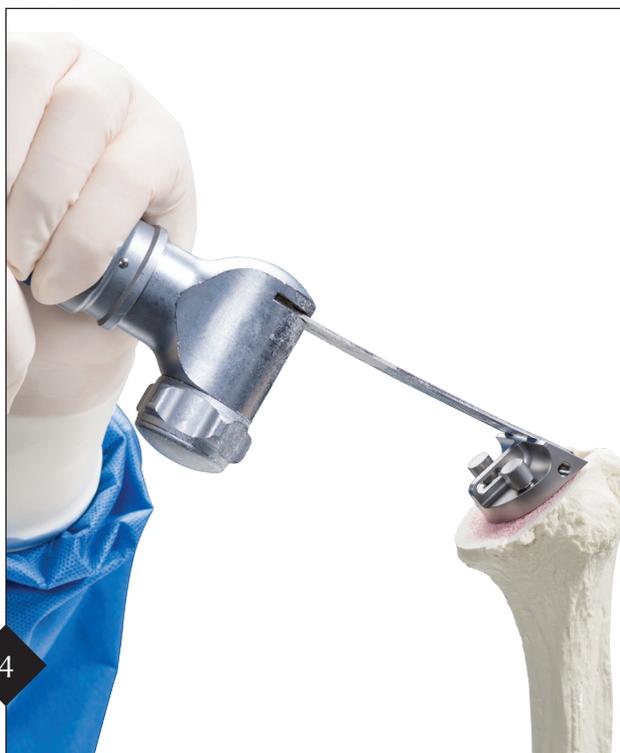
Evaluate the rotator cuff and surrounding soft tissues of the involved shoulder. Upon determining that the rotator cuff tear is irreparable, debride the frayed edges of the remaining cuff and bursa. *Do not perform an acromioplasty or release the coracoacromial ligament, since this may compromise postoperative prosthesis stability.*



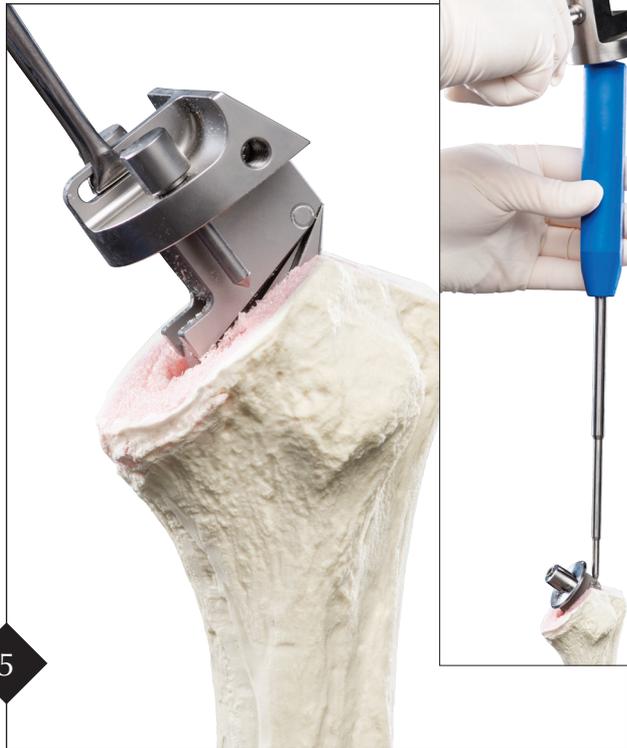
Perform the proximal humeral osteotomy and humeral canal preparation (reaming/broaching) as described in the surgical technique guides for the Univers™ II and Univers Apex total shoulder systems.



The CA Cut Guide is placed in the prepared humeral canal. There is a primary Cut Guide that corresponds with each broach size in the Univers II and Univers Apex Instrument Sets. There is no need to downsize the CA Cut Guide. Verify that the guide is well seated and aligned with the anatomic axis of the humerus (avoid varus or valgus malalignment). Two anchor pegs are impacted into the osteotomy surface for stability.



Perform the greater tuberosity osteotomy with an oscillating saw guided by the CA Cut Guide.



5

Remove the Cut Guide. *Note: The small window in the cutting guide allows forceps to capture the guide for removal.* Place the appropriate-size humeral stem as described in the surgical technique guides for the Univers™ II and Univers Apex total shoulder systems (inset).



6

Place the appropriate size CA Trial Head on the humeral stem. Reduce the humerus and assess shoulder motion, soft-tissue tension, and stability.

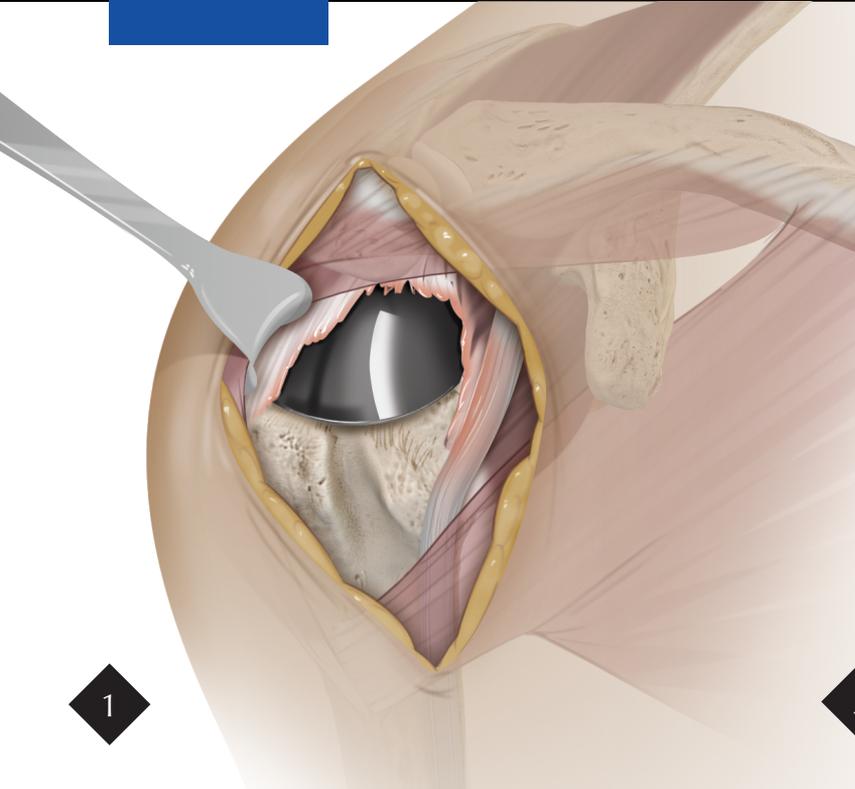


7

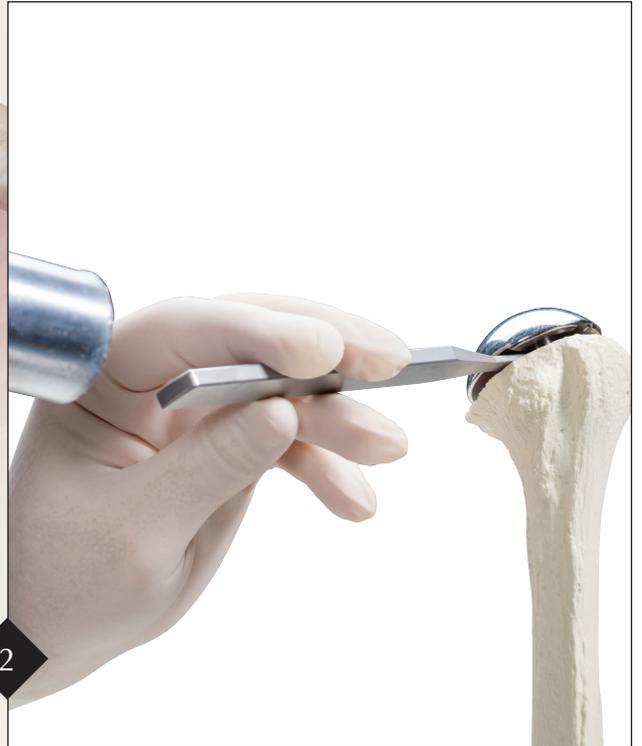
Once the appropriate-size head is determined, dislocate the proximal humerus, remove the trial head, and impact the prosthetic head in place. Reduce the glenohumeral joint and proceed with wound irrigation and closure per surgeon protocol.



Hemiarthroplasty/Total Shoulder Arthroplasty to Hemiarthroplasty With CA Humeral Head



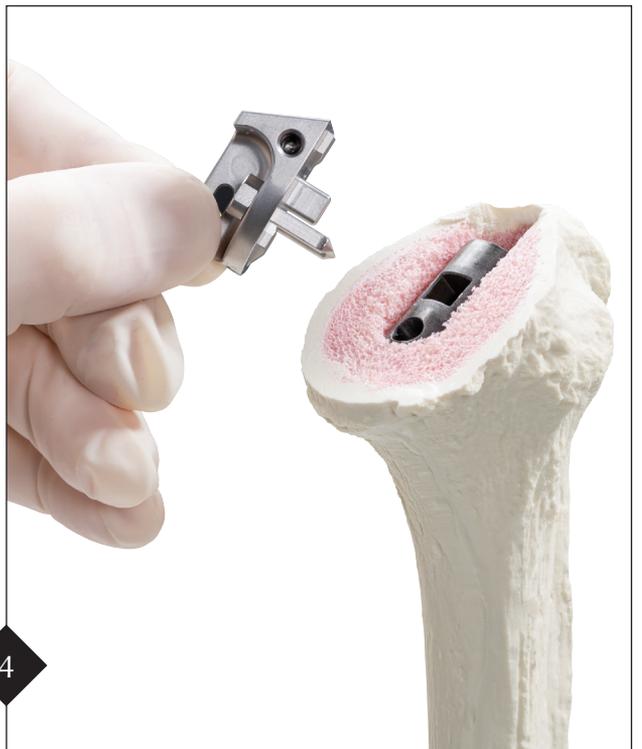
Evaluate the rotator cuff and surrounding soft tissues of the involved shoulder. Upon determining the rotator cuff tear is irreparable, debride the frayed edges of the remaining cuff and bursa. *Do not perform an acromioplasty or release the coracoacromial ligament, since this may compromise postoperative prosthesis stability.*



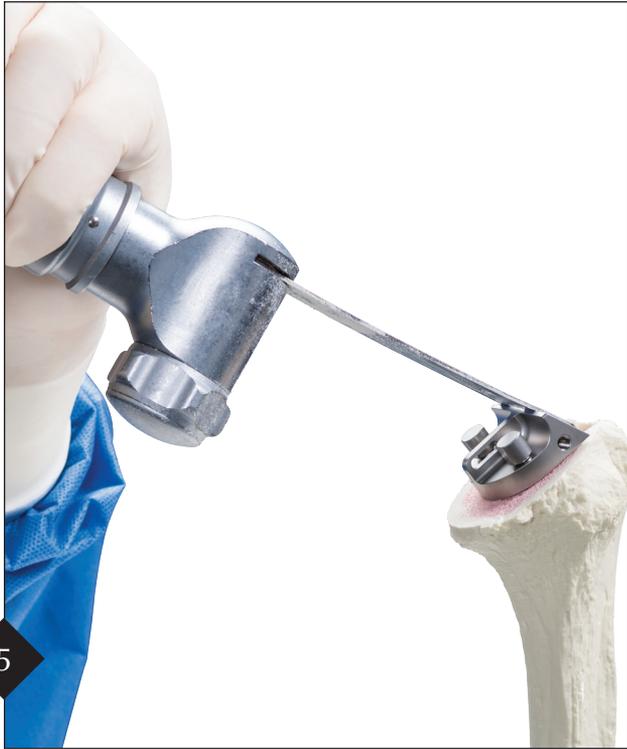
Once the prosthesis is dislocated and the head exposed, remove the prosthetic head with the Humeral Head Extractor. *Note: The Univers™ CA Humeral Head system is not intended for use with glenoid implants.*



The version (superior) screw is completely removed. The Trunion Extractor is threaded into the Morse taper (pictured). The Trunion Extractor is disengaged from the stem by rolling the wrist in a posterior to anterior motion to release the locking mechanism (inset).



Secure the Revision CA Cut Guide to the rectangular recess of the well-fixed stem. Impact the two anchor pegs into the osteotomy surface for stability.



5

Perform the greater tuberosity osteotomy with an oscillating saw guided by the Revision CA Cut Guide.



6

Remove the cutting guide as described in step 5, page 5. Re-engage a new Trunion (inset) and new superior locking screw from the Trunion Replacement Kit and tighten the screw as described in the surgical technique guides for the Univers™ II and Univers Apex total shoulder systems.



7

Remove the guide and place the appropriate size CA Trial Head on the humeral stem. Reduce the humerus and assess shoulder motion, soft-tissue tension, and stability.



8

Once the appropriate-size head is determined, dislocate the proximal humerus, remove the trial head, and impact the prosthetic head in place. Reduce the glenohumeral joint and proceed with wound irrigation and closure per surgeon protocol.

PRIMARY FRACTURE HEMIARTHROPLASTY WITH CA HUMERAL HEAD

Step 1

Perform the proximal humerus canal preparation, fracture stem placement, and preliminary reduction of the tuberosities.

Step 2

Following preliminary reduction, evaluate the quality of the supraspinatus/greater tuberosity and the possibility for healing and function. Upon determining the supraspinatus/greater tuberosity is irreparable and/or of poor quality, determine the appropriate size CA Humeral Head and impact it to the Morse taper of the fracture stem.

Step 3

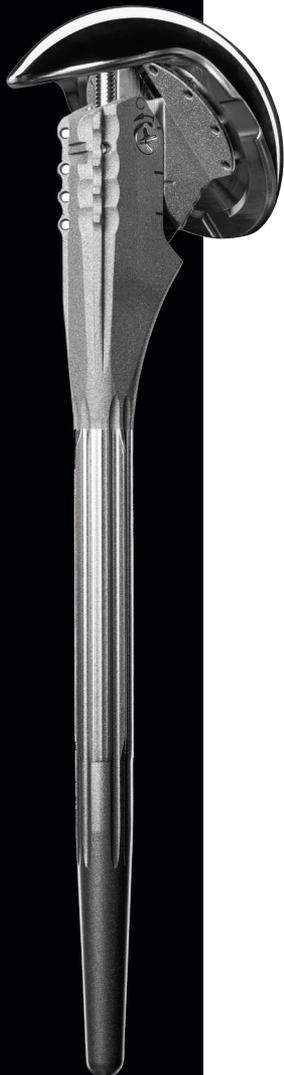
Reduce the Fracture Stem/CA Humeral Head construct and evaluate head height, motion, and stability. Adjust the head height as needed per the UniverTM Fracture system surgical technique and lock it once the appropriate height is determined. Additional trial reductions will be necessary until the appropriate height is determined.

Step 4

Modify the remaining tuberosity bone attached to viable rotator cuff tissue as described in the UniverTM Shoulder Fracture system surgical technique.

Step 5

Reassess tuberosity fixation, motion, and stability prior to closing the superficial layers.



REVISION FRACTURE HEMIARTHROPLASTY TO CA HUMERAL HEAD

Step 1

Once the rotator cuff is exposed during the approach, evaluate the rotator cuff and surrounding soft tissues. Upon determining the rotator cuff tear is irreparable, debride the frayed edges of the remaining cuff and bursa. *Do not perform an acromioplasty or release the coracoacromial ligament, as this may compromise postoperative prosthesis stability.*

Step 2

Once the prosthesis is dislocated and the head exposed, remove the Univer Fracture Humeral Head with the Humeral Head Extractor or an osteotome.

Step 3

The supraspinatus footprint is removed from the superior aspect of the greater tuberosity by a free-hand oscillating saw cut, osteotome, or rongeur.

Step 4

Place the appropriate-size CA Trial Head. Reduce the humerus and assess shoulder motion, soft-tissue tension, and stability.

Step 5

Dislocate the joint and remove the CA Trial Head. If possible, pass sutures for the repair of the subscapularis tendon through the metaphyseal bone just distal to the humeral neck cut.

Step 6

Impact the CA Humeral Head, reduce the prosthesis, and perform closure.

IMPLANTS

Univers CA Humeral Head, 42 mm x 17 mm	AR-9142-17CA
Univers CA Humeral Head, 44 mm x 17 mm	AR-9144-17CA
Univers CA Humeral Head, 44 mm x 19 mm	AR-9144-19CA
Univers CA Humeral Head, 46 mm x 18 mm	AR-9146-18CA
Univers CA Humeral Head, 46 mm x 20 mm	AR-9146-20CA
Univers CA Humeral Head, 48 mm x 19 mm	AR-9148-19CA
Univers CA Humeral Head, 48 mm x 21 mm	AR-9148-21CA
Univers CA Humeral Head, 50 mm x 19 mm	AR-9150-19CA
Univers CA Humeral Head, 50 mm x 21 mm	AR-9150-21CA
Univers CA Humeral Head, 52 mm x 20 mm	AR-9152-20CA
Univers CA Humeral Head, 52 mm x 22 mm	AR-9152-22CA
Univers CA Humeral Head, 54 mm x 21 mm	AR-9154-21CA
Univers CA Humeral Head, 54 mm x 23 mm	AR-9154-23CA
Univers CA Humeral Head, 56 mm x 22 mm	AR-9156-22CA
Univers CA Humeral Head, 56 mm x 24 mm	AR-9156-24CA

UNIVERS™ CUFF ARTHROPATHY INSTRUMENT SET (AR-9200CAS)

Humeral Head, CA, 42 mm x 17 mm	AR-9242-17CA
Humeral Head, CA, 44 mm x 17 mm	AR-9244-17CA
Humeral Head, CA, 44 mm x 19 mm	AR-9244-19CA
Humeral Head, CA, 46 mm x 18 mm	AR-9246-18CA
Humeral Head, CA, 46 mm x 20 mm	AR-9246-20CA
Humeral Head, CA, 48 mm x 19 mm	AR-9248-19CA
Humeral Head, CA, 48 mm x 21 mm	AR-9248-21CA
Humeral Head, CA, 50 mm x 19 mm	AR-9250-19CA
Humeral Head, CA, 50 mm x 21 mm	AR-9250-21CA
Humeral Head, CA, 52 mm x 20 mm	AR-9252-20CA
Humeral Head, CA, 52 mm x 22 mm	AR-9252-22CA
Humeral Head, CA, 54 mm x 21 mm	AR-9254-21CA
Humeral Head, CA, 54 mm x 23 mm	AR-9254-23CA
Humeral Head, CA, 56 mm x 22 mm	AR-9256-22CA
Humeral Head, CA, 56 mm x 24 mm	AR-9256-24CA
CA Cut Guide, size 6	AR-9200-16CA
CA Cut Guide, size 7	AR-9200-17CA
CA Cut Guide, size 8	AR-9200-18CA
CA Cut Guide, size 9	AR-9200-19CA
CA Cut Guide, size 10	AR-9200-20CA
CA Cut Guide, size 11	AR-9200-21CA
CA Cut Guide, size 12	AR-9200-22CA
CA Cut Guide, size 13	AR-9200-23CA
CA Cut Guide, size 14	AR-9200-24CA
CA Cut Guide, size 15	AR-9200-25CA
Revision CA Cut Guide	AR-9200-16CAG
Univers CA Humeral Head Instrument Case	AR-9200CAC



Univers Cuff Arthropathy Instrument Set

OPTIONAL INSTRUMENT SETS

Univers™ II Congruent Glenoid Reamer Set	AR-9200RRS
Shoulder Arthroplasty Retractor Set	AR-9260S-53

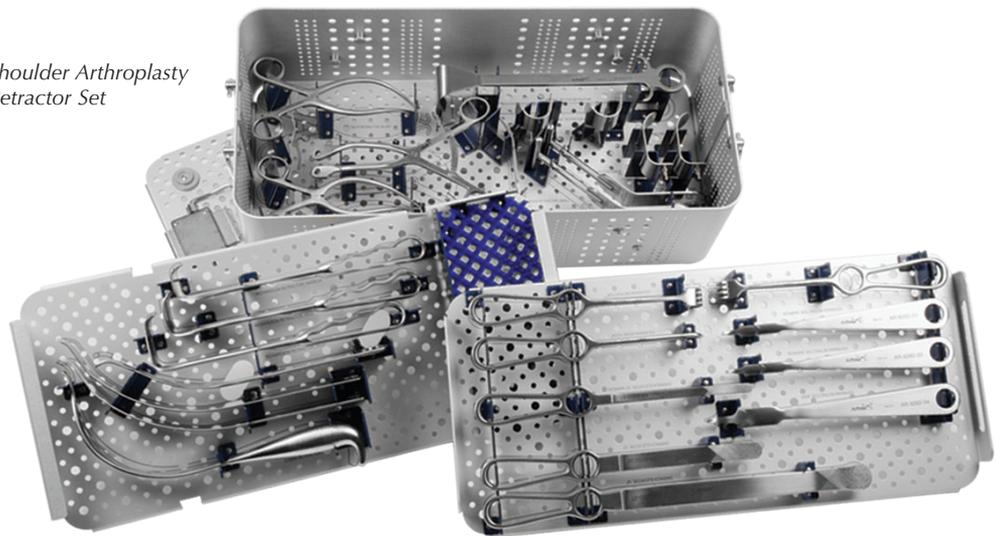
LITERATURE

The Next Generation in Shoulder and Elbow Repair and Reconstruction Technology	LB1-0220-EN
Uniers Fracture Surgical Technique Guide	LT1-0700-EN
Uniers Apex Surgical Technique Guide	LT1-0701-EN
Uniers II Surgical Technique Guide	LT1-0702-EN
Uniers Cuff Arthropathy Head X-ray Templates	AR-706

*Uniers II Congruent
Glenoid Reamer Set*



*Shoulder Arthroplasty
Retractor Set*



WARNINGS

1. An internal fixation device must never be reused. Reuse of this device could result in failure of the device to perform as intended and could cause harm to the patient and/or user.
2. Do not resterilize this device.
3. All metallic implant devices used for this surgical procedure should have the same metallurgic composition.
4. Postoperatively and until healing is complete, fixation provided by this device should be considered temporary and may not withstand weightbearing or other unsupported stress. The fixation provided by this device should be protected. The postoperative regimen prescribed by the physician should be strictly followed to avoid adverse stresses applied to the device.
5. Any decision to remove the device should take into consideration the potential risk to the patient of a second surgical procedure. Implant removal should be followed by adequate postoperative management.
6. Removal of the device should be performed using standard surgical practices for device removal.
7. Preoperative and operating procedures, including knowledge of surgical techniques and proper selection and placement of the device, are important considerations in the successful utilization of this device. The following operative situations may cause premature loosening and complications:
 - Extreme weakening of the bone structure in preparing the bone bed;
 - Unsuitable selection of the implant size;
 - Inadequate cleaning of the bone bed prior to implantation; and
 - Excessive use of force in placing or fastening the implant, provoking splintering fractures or causing the bone to tear
8. The appropriate Arthrex[®] delivery system is required for proper insertion of the implant.
9. Only Arthrex delivery systems, instruments, and trial prostheses should be used for the implantation procedure.
10. Endoprostheses may not be processed mechanically or changed in any other way.
11. Do not implant any parts that have been scratched or damaged. An artificial joint is subject to wear and/or can loosen over a period of time. Wear and loosening may make it necessary to reoperate on an artificial joint.
12. An infection in an artificial joint may lead to implant removal.
13. This device should only be used in conjunction with other implants designed specifically for use with this system.
14. This device has not been evaluated for safety and compatibility in the magnetic resonance (MR) environment. This device has not been tested for heating or migration in the MR environment. If the implant is manufactured from a metallic material, surgeons can expect that MR artifacts will be present during routine MR imaging.

INDICATIONS

The Univers[™] CA Heads are indicated for use in hemi-shoulder replacement. Hemi-shoulder replacement is indicated for: a severely painful and/or disabled joint resulting from osteoarthritis, traumatic arthritis, or rheumatoid arthritis; fracture-dislocations of the proximal humerus where the articular surface is severely comminuted, separated from its blood supply, or where the surgeon's experience indicates that alternative methods of treatment are unsatisfactory; other difficult clinical problems where shoulder arthrodesis or resection arthroplasty is not acceptable (eg, revision of a failed primary component).

Hemi-shoulder replacement is also indicated for:

- Ununited humeral head fractures
- Avascular necrosis of the humeral head
- Rotator cuff tear arthropathy
- Deformity and/or limited motion

The Univers CA Heads are intended to be used with the Univers Shoulder Stem for cemented or uncemented fixation.

In Canada: The Univers CA Heads are intended for hemiarthroplasty in shoulder arthritis and trauma where the rotator cuff is not functional and not reconstructable. The CA heads are not intended to be used with glenoid components.

CONTRAINDICATIONS

1. Patients who are not anatomically and structurally suited to receive the selected implant, or who do not have a functional deltoid muscle.
2. Insufficient quantity or quality of bone.
3. Blood supply limitations and previous infections, which may retard healing.
4. Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made and sensitivity ruled out prior to implantation.
5. Any active infection or blood supply limitations.
6. Conditions that tend to limit the patient's ability or willingness to restrict activities or follow directions during the healing period.
7. The use of this device may not be suitable for patients with insufficient or immature bone. The physician should carefully assess bone quality before performing orthopedic surgery.

For a complete listing of instructions, warnings and contraindications, please review the Directions For Use on Arthrex.com or packaged with the device.



This description of technique is provided as an educational tool and clinical aid to assist properly licensed medical professionals in the usage of specific Arthrex products. As part of this professional usage, the medical professional must use their professional judgment in making any final determinations in product usage and technique. In doing so, the medical professional should rely on their own training and experience, and should conduct a thorough review of pertinent medical literature and the product's Directions For Use. Postoperative management is patient specific and dependent on the treating professional's assessment. Individual results will vary and not all patients will experience the same postoperative activity level or outcomes.

View U.S. Patent information at www.arthrex.com/corporate/virtual-patent-marking

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